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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,917	02/24/2004	Peng Cho Tang	034536-1150	1976
22428	7590	10/12/2005	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			STOCKTON, LAURA	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/784,917	TANG ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-17 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,12 and 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on February 24, 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/24/04&5/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

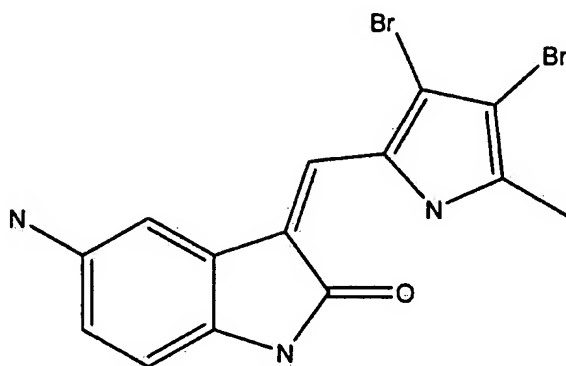
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DETAILED ACTION

Claims 7-17 are pending in the application.

Election/Restrictions

Applicants' election with traverse of Group I, and the species of the third compound in Table 10 on page 115 of the instant specification (reproduced below), in the reply filed on July 14, 2005 is acknowledged.



The traversal is on the ground(s) that there is no undue burden to examiner to examine Groups I and II together. Applicants also argue that rejoinder is required under *In re Ochiai*.

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Applicants' arguments have been considered but have not been found persuasive. Each of the groups outlined in the restriction requirement involve separate search considerations, not just class and subclass searches. Even the elected group of Group I could not be searched in its entirety. Note the below identified scope of the examined invention. Therefore, it would be an undue burden on the Examiner and the Patent Office's resources if the instant application were unrestricted.

Further, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended

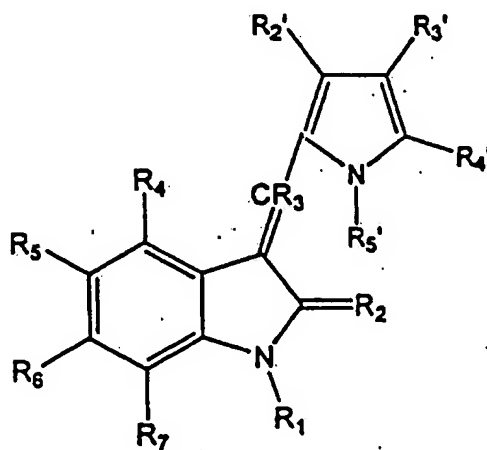
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during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

The requirement is still deemed proper and is therefore made FINAL.

The scope of the examined invention that has been examined, inclusive of the elected species, is as follows:

Compounds of the formula (formula found on page 50, starting at line 8 through to the top of page 51, lines 1-5 of the instant specification)



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wherein R_1 is hydrogen; R_2 is oxygen; one of R_4 , R_5 , R_6 or R_7 represents NRR' ; all other variables are as defined under the formula on page 50, starting at line 8 through to the top of page 51, lines 1-5 of the instant specification. The scope of the examined invention is embraced by instant claims 9-11 and 13 (all in-part).

Subject matter not embraced by the above identified scope of the elected invention and claims 7, 8, 12 and 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on July 14, 2005.

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Information Disclosure Statement

The Information Disclosure Statements filed on February 24, 2004 and May 5, 2004 been considered by the Examiner. Each of the references lined-through in the 26 page IDS filed February 24, 2004 was done so because the reference was either: (1) not legible; (2) not properly/clearly identifiable; or (3) no copy of the reference was found in any of the previous applications.

Drawings

The drawings are objected to because there are a number of drawings that are not clear or illegible. See Figures 5 of 12; 11 of 12; 8-25 of 30; 29 of 30; and 30 of 30.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office

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action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the following, an "and" should replace "or" before the last substituent listed in each of the occurrences for proper Markush language:

(1) claim 9, under definition (c), R₁₀ variable;

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(2) claim 9, under definition (d), R_{11} , R_{12} and R_{13} variables;

(3) claim 10, under definition R_5 (iii), R_{10} variable;

(4) claim 10, under definition R_5 (iv), R_{11} , R_{12} and R_{13} variables;

(5) claim 10, under definition R_1 (iii), R_{21} variable;

(6) claim 10, under definition R_1 (iv), R_{22} , R_{23} and R_{24} variables;

(7) claim 10, under definition R_4 , R_6 and R_7 (iii), R_{32} variable; and

(8) claim 10, under definition R_4 , R_6 and R_7 (iv), R_{33} , R_{34} and R_{35} variable, and a comma is needed after R_{33} ;

In claim 9, an "and" should be added after definition (i).

In claim 10, an "and" should be added after definition (ix) under the R_5 definition.

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In claim 11, an "and" is needed before definition (9).

Claim 13 is indefinite because the claim depends from cancelled claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 9-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 53 of copending Application No. 10/458,730 {US 2004/0067531}. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically described in copending Application No. 10/458,730.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating arthritis).

One skilled in the art would thus be motivated to prepare compounds embraced by copending Application No. 10/458,730 to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for

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example, arthritis. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 9-11 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5 and 10-14 (see especially claim 4) of U.S. Patent No. 5,792,783; claims 1 and 2 of U.S. Patent No. 6,906,093; claims 1-3, 6-8, 1-12 and 21 (see especially claim 12) of U.S. Patent No. 6,486,185; and claims 1-5, 14 and 15 (especially claim 14) of U.S. Patent No. 6,531,502. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

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instant claimed compounds are generically described in each of the patents.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating arthritis).

One skilled in the art would thus be motivated to prepare compounds embraced by the patents to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for example, arthritis. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al. {WO 96/40116} and Tang et al. {U.S. Pat. 5,792,783}, each taken alone or in combination with each other.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim indolinone compounds. Tang et al. '116 {the compounds of formula (III) wherein R₁ is hydrogen; R₂ is oxygen; R₄, R₆ and R₇ are each hydrogen; R₅ is NRR'; R and R' are each hydrogen; and A is an optionally substituted pyrrole ring, said substituents being alkyl, halogen, etc. on pages 16, 17, 24-29; and

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especially the compound on page 16, lines 23-24} and Tang et al. '783 {formula (III) in column 5, lines 1-38; column 6, lines 55-61; columns 15-19; and especially compound 5.9 in column 21} each teach indolinone compounds that are structurally similar to the instant claimed compounds.

***Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)***

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

***Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar

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compounds would possess similar activity (e.g., treating arthritis).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for example, arthritis. Since each of the Tang et al. references teach similar compounds to each other, the combination of these references would also teach Applicants' claimed invention. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

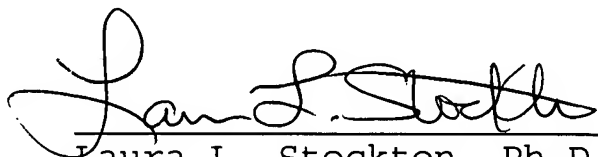
The elected species is not allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

October 3, 2005